

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference F2-A0301P	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/018042	International filing date (<i>day/month/year</i>) 03.12.2004	Priority date (<i>day/month/year</i>) 05.12.2003
International Patent Classification (IPC) or national classification and IPC C12N15/31, 1/15, 1/19, 1/21, 5/00, C07K14/205, 16/12, C12P21/02, C12Q1/68, G01N33/50, 33/569		
Applicant FUSO PHARMACEUTICAL INDUSTRIES, LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1.	Statement
	Novelty (N)
	Claims 1-30 YES
	Claims NO
	Inventive step (IS)
	Claims YES
	Claims 1-30 NO
	Industrial applicability (IA)
	Claims 1-30 YES
	Claims NO
2.	Citations and explanations (Rule 70.7)
	Document 1: Infect. Immun., 1996, 64 (6), pages 2070 to 2078
	Document 2: J. Appl. Microbiol., June 2003, 94 (6), pages 1003 to 1014
	Document 3: J. Med. Microbiol., 2001, 50 (12), pages 1087 to 1094
	Document 4: J. Clin. Microbiol., 1999, 37 (5), pages 1646 to 1650
	Document 5: Appl. Environ. Microbiol., 1999, 65 (4), pages 1501 to 1505
	Document 6: J. Clin. Microbiol., September 2003, 41 (9), pages 4071 to 4080
	<p>The inventions set forth in claims 1 to 30 do not involve an inventive step in the light of documents 1 to 6 cited in the international search report.</p> <p>Document 1 presents the amino acid sequences of the CdtA protein, the CdtB protein and the CdtC protein from <i>Campylobacter jejuni</i> (hereinafter, <i>C. jejuni</i>), as well as the genes that encode said proteins (in particular, refer to fig. 2, GenBank accession number U51121). In addition, document 1 indicates that the cdtB probe from <i>C. jejuni</i> is capable of hybridizing with gene fragments from</p>

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various strains of *C. jejuni* or various strains of *Campylobacter coli* (hereinafter, *C. coli*), but does not hybridize with gene fragments from *Campylobacter fetus* (hereinafter, *C. fetus*); indicates that the *cdtB* probe from *C. coli* is capable of hybridizing with gene fragments from various strains of *C. jejuni* or various strains of *Campylobacter coli* (hereinafter, *C. coli*); indicates that partial fragments of the *cdtB* genes from *C. jejuni*, *C. coli* and *C. fetus* were amplified by means of the degenerative primer VAT2 and the degenerative primer WMI1; and presents the amino acid sequence of the CdtB protein from *C. fetus* (in particular, refer to the section titled 'Hybridization and PCR Studies,' fig. 2 and 6).

Meanwhile, documents 2 to 6 present general primers for amplifying the *cdtA* gene, the *cdtB* gene, the *cdtC* gene and other *cdt* genes from *C. jejuni* and *C. coli*. In addition, document 6 describes a technique for identifying the species of microorganisms that belong to the genus *Campylobacter* by means of a DNA microarray.

Claims 1 to 6

Prior to the filing of the present application, it was known practice for a person skilled in the art to acquire a gene that encodes a given protein and then attempt to acquire genes that encode corresponding proteins from organisms that belong to closely related species; thus, it would have been easy for a person skilled in the art to acquire the genes that encode the CdtA protein, the CdtB protein and the CdtC protein from *C. coli* and *C. fetus*, which belong to the same genus as *C. jejuni*, by means of the inventions presented in

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documents 1 to 6 and genetic engineering techniques that were well-known prior to the filing of the present application. In addition, a person skilled in the art could prepare recombinant proteins by means of host cells carrying vectors that include said genes, and could prepare antibodies against said recombinant proteins, as appropriate.

Claims 7 to 30

Prior to the filing of the present application, it was common practice to detect for the presence or the absence of microorganisms that belong to the genus *Campylobacter*, and techniques for detecting the presence or the absence of microorganisms that belong to a given genus by means of a primer interacts with all of the microorganisms that belong to said genus were well known prior to the filing of the present application. Such being the case, it would have been easy for a person skilled in the art to conceive of attempting to detect the presence of microorganisms that belong to the genus *Campylobacter* by means of the general primers presented in documents 1 to 6; likewise, it would also have been easy for a person skilled in the art to conceive of acquiring sequence information for the genes that encode the CdtA protein, the CdtB protein and the CdtC protein thereof based on the inventions presented in documents 1 to 6 and the well-known techniques indicated above, designing another general primer and then using said general primer in order to detect the presence of other microorganisms that belong to the genus *Campylobacter*.

In addition, techniques for identifying the species of different microorganisms that belong to the genus

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Campylobacter are well known, as presented in document 6, and techniques for identifying the species of a given microorganism by means of primers that specifically interact with one species but not with other species that belong to the same genus were well known prior to the filing of the present application. Such being the case, it would have been easy for a person skilled in the art to conceive of acquiring the sequence information for the genes that encode the CdtA protein, the CdtB protein and the CdtC protein based on the inventions presented in documents 1 to 6 and the well-known techniques indicated above in an attempt to acquire a primer that detects only one species among *C. coli*, *C. jejuni* or *C. fetus* but not the other species.

Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

Example 8 includes the disclosure "by means of the general primer (1) obtained in example 6." However, example 6 pertains to the acquisition of general primer (2); therefore, the contents of the examples in question do not conform to one another.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☒ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed
- ☐ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purposes of search and/or examination
- ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."